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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/512,124

08/26/2005

Genhong Cheng

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20350 7590 02/18/2010  
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EXAMINER

DANG, IAN D

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/512,124	<b>Applicant(s)</b> CHENG ET AL.	
	<b>Examiner</b> IAN DANG	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5,20 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5,20 and 25-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/26/2010 has been entered.

#### ***Status of Application, Amendments and/or Claims***

The amendment of 26 January 2010 has been entered in full. Claims 1-4, 6-19, 21-24 have been cancelled.

Claims 5, 20, 25-31 are under examination.

#### ***Rejection Maintained***

#### ***Claim Rejections - 35 USC § 112, First paragraph (Enablement)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 20, 25-31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **a method for reducing viral infection and replication of the Murid herpesvirus 68 (MHV68) in a cell *in vitro* and *in vivo***, does not reasonably provide enablement for a method for inhibiting viral infection and viral replication in a cell *in vitro* or *in vivo* or a method of inhibiting a viral infection in a human. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

At page 4 of the response, Applicants indicate that the Office Action acknowledged that the specification provided sufficient guidance for the inhibition of a viral infection of a cell *in vitro*. However, the Examiner was concerned about enablement of the *in vivo* subject matter of the claims. To address this remaining concern, the Applicants provide a declaration with experimental data showing the claimed subject matter works *in vivo* in accordance with the teachings of the specification.

The declaration under 37 CFR 1.132 filed 01/26/2010 is insufficient to overcome the rejection of claims 5, 20, 25-31 based upon the rejection 35 U.S.C. 112, first paragraph, as set forth in the last Office action because Applicants have still not provided sufficient evidence for the inhibition of a viral infection in a cell *in vivo* or in a human and a method of inhibiting a viral replication in a cell *in vivo*. More specifically, based on the results shown in Exhibit A (therapeutic affect of pIC treatment on MHV68 infection) presented in the declaration the inventor concludes that “the luciferase assay, the experimental treatment with poly I:C greatly reduced the level of lung infection” (see page 2 of the declaration). In addition, based on the results shown in Exhibit B (Prophylactic affect of pIC treatment on MHV68 infection) presented in the declaration filed 01/26/2010 the inventor concludes that “as compared to a control (saline) group, prior administration of poly I:C to the mice greatly reduced the level of infection in mice administered a challenge dose of MHV68” (see page 2 of the declaration). The declaration provides evidence for reduced level of infection in mice that have been administered poly I:C, but it is not sufficient to support inhibition of viral inhibition or replication in a cell *in vitro*, *in vivo*, or in a human.

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In addition, the Examiner has reconsidered its position regarding the enablement for the method of inhibiting viral infection and replication *in vitro* in view the declaration filed by one of the inventor indicating that the administration of poly I:C reduced the level of infection in mice. Based on the specification and Exhibits A and B in the declaration, they provide support for a reduction in the level of viral infection and replication in a cell, but do not provide support the inhibition of viral infection and replication in a cell as recited in the claims of the instant application.

Therefore, the claimed invention does not meet the requirements to enable the claimed method for inhibiting viral infection and viral replication in a cell *in vivo* and *in vivo* and the claimed method of inhibiting a viral infection in a human.

Furthermore, the role of poly I:C in anti-viral responses has not been established in the art, since numerous references indicate a large amount of variability in decreasing viral infection. More specifically, the reference by Egyed (US patent 7,148,191; filed June 7, 2001; published August 28, 2003; issued December 12, 2006) teaches that:

Polyinosinic-polycytidylic acid (poly I:C) is known as a potent interferon type I inducer (Manetti et al., 1995). Because of its protective effects in a number of animal species against a broad spectrum of both RNA and DNA viruses (e.g., herpes simplex virus, rabies virus, Japanese B encephalitis virus, vaccinia virus, encephalomyocarditis virus), poly I:C is often used in models of viral infections. Changes that occur in response to poly I:C are thought to be representative of changes that occur in response to a variety of different viruses. poly I:C is known to stimulate macrophages to produce cytokines such as IL-1a and IL-12 (Manetti et al., 1995), it is a potent NK cell stimulator (Cavanaugh et al., 1996) and, in general, the poly I:C compound is known to promote Th1-specific immune responses. Because of these abilities, poly I:C has been widely applied as an immunomodulator in several clinical trials showing little or no toxicity (Guggenheim et al., 1977, Simnaler et al., 1977). However, there was no patient benefit (column 1, line 66, to column 2, line 16).

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However, the post-filing reference by Matsumoto (2008, Advanced Drug Delivery Reviews, Volume 60, pages 805-812) teaches that the role of poly I:C mediated by the activation of the TLR3 receptor in an anti-viral infection is highly variable due to numerous factors. For instance, the reference by Matsumoto teaches that the role of TLR3 in the anti-viral response appears to be dependent on the viral of the genome structure, entry route into the cells, viral affecting sites and property of the host anti-viral effector functions (page 809, left column, second full paragraph).

Based on these teachings the use of poly I:C to induce viral infection in a subject is unpredictable for the inhibition of viral infection by contacting a cell with poly I:C by stimulating interferon regulatory factor in a subject and requires undue experimentation.

### ***Conclusion***

No claim is allowed.

### ***Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
February 15, 2010

/Robert Landsman/  
Primary Examiner, Art Unit 1647